REMARKS

Applicants respectfully request reconsideration of this application in view of the above amendments and the following remarks.

Claims 1, 3, 5, 6, 8, 10, 12, 14 and 15 are pending, of which claims 1, 6, 8, 10, 12, and 14 are independent. The remaining claims have been canceled. The pending claims have been amended to recite the laxative is bisacodyl, as discussed below.

In the last Office Action mailed September 10, 2003, Claims 1-3, 5-15 and 17 were rejected under 35 U.S.C. §112, first paragraph, as not enabled by the specification. The Examiner argued that the specification does not reasonably provide enablement for vanilloid compounds, including capsaicin. Although Applicants disagree with this rejection, as previously noted, in order to advance the prosecution, subject matter directed to the use of vanilloid compounds has been deleted from the claims herein. Applicants reserve the right to pursue this subject matter in one or more divisional applications.

Claims 1, 3, 5, 6, 8, 10, 12, 14 and 15 were rejected under Section 103(a) as obvious over Drug Launches (1993) in view of the acknowledged prior art, Schmidt et al. (US 5,424,064), Holtman et al. and Sable et al. for the reasons of record.

Drug Launches (1993) was previously cited to show a composition containing bisacodyl and simethicone, and methods of using the same to treat constipation, facilitate bowel motion and evacuation of the intestines. See Office Action mailed September 9, 2002.

The Examiner also pointed to applicants' specification (page 1, lines 27-31), which references US 5,418,220 disclosing simethicone used in the treatment of constipation. Then, based on Holtman et al., the Examiner argued that the prior art further suggests it is known that simethicone is suitable for treating disturbed gastrointestinal motility. The Examiner stated, "the prior art teaches the combination of bisacodyl and simethicone and that fullness or bloating are gas-related or linked to disturbed gastrointestinal motility (See Holtman et al.). As such, one of ordinary skill in the art would be motivated to combine bisacodyl and simethicone with the expectation that the combination would be more effective in treating fullness or bloating" and "Holtman et al. does suggest that simethicone is effective in increasing gastrointestinal motility in that the effects of simethicone are 'not limited to gas-related symptoms.'"

Applicants maintain that this combination of references does not teach or suggest the claimed invention. Drug Launches describes the product Purgo-Pil, in which bisacodyl is the sole active ingredient. Simethicone is present, but only as an excipient in the coating. It was undoubtedly used to facilitate the coating process, and is not present as an active ingredient. Further, no amount of simethicone is given, and clearly there is no teaching or suggestion of simethicone's effect on laxatives such as bisacodyl.

Holtman reports on a study undertaken to compare simethicone with cisapride in treating functional dyspepsia. A full account of the study is given in the enclosed publication, "Randomized Double-blind Comparison of Simethicone with Cisapride in Functional Dyspepsia," *Aliment. Pharmacol. Ther.* (1999) 13:1459--1465. Applicants request that this reference be made of record in this application, and enclose a Form PTO-1449 for this purpose. The Holtman study found that simethicone relieved the symptoms of dyspepsia during the first two weeks of treatment better than cisapride. However, the mechanism of action of the simethicone was not found. The authors state on page 1459, second column, "[i]n patients with functional dyspepsia, fullness or bloating are believed to be gas-related, linked to disturbed GI motility, or reflect heightened perception of gas or disturbed motility." On page 1464, the authors state that simethicone may act on the surface tension to reduce gas, or stimulate gastrointestinal motility and therefore accelerate the propulsion and expulsion of gas. They also note that simethicone appears to influence symptoms such as pain and satiety or reflux that are not believed to be directly gas-related. They conclude, "[t]hus, the precise mechanism of action still remains to be elucidated."

Applicants' own data in Example 1 of the present application should also be noted. Applicants found the use of simethicone alone had no effect on small bowel transit in rats treated therewith.

Accordingly, the Examiner's assertion that simethicone is known to increase intestinal motility appears to be speculative at best. First, it is contradicted by applicants' data. Second, it is unsupported by the Holtman authors, who are admittedly unsure about the mechanism of action of simethicone.

As previously urged by applicants, this kind of alternative information cannot suggest the claimed invention, except by hindsight analysis. The claimed invention rests on the specific recognition that the combination of bisacodyl with simethicone in an amount of about 10 mg to

about 500 mg per dose provides an enhanced laxative product. Claim 14 in particular, which recites a method for enhancing the efficacy of bisacodyl comprising administering to a human an effective amount of bisacodyl with about 10 mg to about 500 mg per dose of simethicone, is certainly neither taught nor suggested by the references cited by the Examiner.

For these reasons, applicants again submit that the claims as amended are patentable. Early and favorable reconsideration is requested.

Respectfully submitted,

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Dated: 2/10/04